UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/696,423 | 10/29/2003 | Asher Porath | 084/03739 | 6758 |

44909 7590 03/07/2007

WOLF, BLOCK, SCHORR & SOLIS-COHEN LLP
250 PARK AVENUE
NEW YORK, NY 10177

| EXAMINER | |
|---|---|
| BROWN, HELENE C | |
| ART UNIT | PAPER NUMBER |
| 3768 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/07/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/696,423 | PORATH, ASHER | |
| | Examiner | Art Unit | |
| | Helene Bor | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/29/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Priority*

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on 10/29/2003 complied with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Specification*

3. The disclosure is objected to because of the following informalities:

a. Page 10 Line 24 – "images of slices --29-- of the breast"

b. Page 11 Line 19 – "combination computer controller --31-- and"

c. Page 11 Line 22 – "selected planes --29-- in the breast --17--"

d. Page 11 Line 26 – " a given plane --29--."

e. Page 11 Line 33 – " the detector --24--. "

Appropriate correction is required.

### *Drawings*

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "19 & 19a" has been used to designate both contact window and contact plate. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one

figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

5. Claim 1 is objected to because of the following informality: "the breast" lacks proper antecedent basis and should be "a breast". Appropriate correction is required.

6. Claim 4 is objected to because of the following informality: "non-radient" should be spelled --non-radiant--.

### *Claim Rejections - 35 USC § 101*

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. By use of the term "the breast" in claim 14, the claim improperly defines the structure in relation ship to a living being.

### *Double Patenting*

*Nonstatutory Rejection*

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 6, 14-19, 21-22 & 25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 4-8, 11-12 & 24-28 of U.S. Patent No. 6,668,187 B1. For double patenting to exist as between the rejected claims and patent claim 4-8, 11-12 & 24-28, it must be determined that the rejected claims are not patentably distinct from claim 4-8, 11-12 & 24-28. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claim 4-8, 11-12 & 24-28 and, if so, whether those differences render the claims patentably distinct.

Rejected claim 6 is merely broader than claim 11 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 14 is merely broader than claim 4 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 15 is merely broader than claim 5 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 16 is merely broader than claim 6 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 17 is merely broader than claim 7 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 18 is merely broader than claim 8 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 19 is merely broader than claim 12 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 21 is merely broader than claim 21 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 22 is merely broader than claim 22 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 25 is merely broader than claim 26 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 26 is merely broader than claim 27 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

Rejected claim 27 is merely broader than claim 28 of the patent. Therefore, it is "anticipated" since it would be obvious to make broader (*In re Goodman*).

10. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims read on each other. It is clear that all the elements of claim 6, 14-19, 21-22 & 25-27 are to be found in claim 4-8, 11-12

& 24-28. The difference between claim 6, 14-19, 21-22 & 25-27 of the application and claim 4-8, 11-12 & 24-28 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus, the invention of claim 4-8, 11-12 & 24-28 of the patent is in effect a "species" of the "generic" invention of claim 6, 14-19, 21-22 & 25-27. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 6, 14-19, 21-22 & 25-27 is anticipated by claim 4-8, 11-12 & 24-28 of the patent, it is not patentably distinct from claim 4-8, 11-12 & 24-28.

11. The examiner acknowledges that Application 10/696423 is a divisional from U.S. Patent No. 6,668,187 B1. However, the divisional was filed not out of necessity from a restriction by the examiner. A double patenting rejection is therefore proper.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1-6 & 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Carroll'165 (US Patent No. 4,515,165).

**Claim 1:** Carroll'165 teaches an apparatus for imaging of the inner structure of the breast (Abstract). Carroll'165 teaches a source of light

illuminating the breast when the source of light is situated at a first position of the breast (Col. 3, Line 52 – Col. 4, Line 9). Carroll'165 teaches a detector which when situated at a second position relative to the breast, detects light from said source passing through a portion of the breast from the source (Col. 3, Line 65 – Col. 4, Line 2). Carroll'165 a source of light comprising either a non-laser radiant source, a laser source or a tunable light source (Col. 5, Line 43-54). Carroll '165 also teaches using at least one optical filter situated between source and the detector that limits the light reaching the detector from the source (Col. 5, Line 54-64). Carroll'165 teaches using the apparatus at a range of 400 to 700 and regular intervals (Col. 5, Line 43-58).

**Claim 2/1:** Carroll'165 teaches an apparatus wherein the apparatus comprises a non-laser spectral source of light and an optical filter of the at least one optical filters having a lower pass-band limit of 520 nanometers or more and an upper pass-band limit of 580 nanometers or less (Col. 5, Line 54-58).

**Claim 3/1:** Carroll'165 teaches an apparatus wherein the apparatus comprises a non-laser spectral source of light and an optical filter of the at least one optical filters having a lower pass-band limit of 490 nanometers or more and an upper band-pass limit of 510 nanometers or less (Col. 5, Line 54-58).

**Claim 4/1:** Carroll'165 teaches an apparatus wherein the source of light is a non-radiant laser source. In addition, Carroll'165 teaches an apparatus including a plurality of optical filters (Figure 5, Element 60). Carroll'165 teaches an apparatus wherein a filter holder (Figure 5, Element 50) situated between the source and the detector. Carroll'165 teaches an apparatus wherein the filter limits

to a visible spectral band different from that of at least one of the other filters and wherein at least one of the filters transmits in a range outside the red and infra-red (Col. 10, Line 9-16). Carroll'165 teaches an apparatus wherein means for selectively changing the filter in the holder (Figure 5, Element 60).

**Claim 5/1:** Carroll'165 teaches an apparatus wherein the source of light comprises an incandescent light source (Col. 5, Line 50-54).

**Claim 6/1:** Apparatus according to claim 1 wherein the source of light comprises a high intensity discharge light source (Col. 5, Line 50-54).

**Claim 10/7/1:** Carroll'165 teaches an apparatus wherein the laser source provides a tunable laser output (Col. 5, Line 50-54).

**Claim 11/10/7/1:** Carroll'165 teaches an apparatus wherein the laser is tunable to a wavelength above 620 nanometers (Col. 5, Line 43-58).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 7-9 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll'165 (US Patent No. 4,515,165).

**Claim 7/1:** Carroll'165 teaches an apparatus wherein the source of light comprises a laser source having an output in the visible spectral band (Col. 5, Line 54-58). Carroll'165 does not specifically teach excluding the red, however, Carroll'165 does each using certain ranges depending upon the tissue environment involved (Col. 20, Line 35-42). One could use Carroll'165 teachings to exclude to include which visible light range one desired or needed.

**Claim 8/7/1:** Carroll'165 teaches an apparatus wherein the source of laser light has an output at between 490 and 510 nanometers (Col. 5, Line 54-58).

**Claim 9/7/1:** Carroll'165 teaches an apparatus wherein the source of laser light has an output at between 520 and 580 nanometers (Col. 5, Line 54-58).

**Claim 20:** Carroll'165 teaches a method of imaging a breast (Col. 2, Line 5-8). Carroll'165 teaches illuminating the breast (Col. 2, Line 35-46). Carroll'165 teaches forming an image of said illumination passing through a portion of the breast (Col. 18, Line 41-43). Carroll'165 teaches limiting the light used for imaging to a visible spectral band wherein the visible spectral band is limited to the ranges between 520 and 580 nanometers and between 490 and 520 nanometers (Col. 5, Line 54-58). Carroll'165 does not specifically teach

excluding the red, however, Carroll'165 does each using certain ranges depending upon the tissue environment involved (Col. 20, Line 35-42). One could use Carroll'165 teachings to exclude to include which visible light range one desired or needed.

**Claim 21/20:** Carroll'165 teaches a method wherein the visible spectral band is limited to a band having a lower band limit of at least 520 nanometers and an upper band limit of below 580 nanometers (Col. 5, Line 43-58 Col. 20, Line 35-42).

**Claim 22/20:** Carroll'165 teaches a method wherein the visible spectral band is limited to a band having a lower band limit of at least 490 nanometers and an upper band limit of below 510 nanometers (Col. 5, Line 43-58 & Col. 20, Line 35-42).

**Claim 23/20:** Carroll'165 teaches a method for separately imaging the breast at a plurality of wavelengths or wavelength bands (Col. 10, Line 9-16). Carroll'165 does not specifically teach excluding the red and infra-red, however, Carroll'165 does each using certain ranges depending upon the tissue environment involved (Col. 20, Line 35-42). One could use Carroll'165 teachings to exclude to include which visible light range one desired or needed.

**Claim 24/23/20:** Carroll'165 teaches a method wherein at least one of the images is generated from light having a wavelength greater than 620 nanometers (Col. 5, Line 43-58 & Col. 20, Line 35-42).

**Claim 25/20, 26/20, & 27/20:** Carroll'165 teaches a method utilizing wavelengths of light in producing images such that larger blood vessels, fine blood vessels and tumor tissue is emphasized (Col. 8, Line 65 – Col. 9, Line 19).

17. Claim 12-16 & 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll'165 (US Patent No. 4,515,165) and in further view of Siczek'447 (US Patent No. 5,386,447).

**Claim 12:** Carroll '165 fails to teach stereotactic images of a breast. However, Siczek'447 teaches an apparatus for obtaining stereotactic images of the interior of a breast (Col. 9, Line 7-22) and sterotactic image is perceived by a viewer (Col. 9, Line 7-22). It would have been obvious to combine the teachings of Carroll'165 and Nelson'974 in order to direct minimally invasive surgical techniques (Col. 9, Line 40-45). Carroll'165 teaches an apparatus at least one source of light illuminating the breast and situated at a first position of the breast (Col. 3, Line 52 – Col. 4, Line 9). Carroll'165 teaches an apparatus at least one matching interface situated, at a second position, on a surface of the breast, which reduces scatter caused by said surface (Col. 3, Line 17 & Figure 5, Element 60). Carroll'165 teaches an apparatus a pair of spaced imaging detectors that view a portion of the breast through said at least one interface and produce images of said portion (Col. 3, Line 65 – Col. 4, Line 2 & Figure 14A, Element 218). Carroll'165 teaches an apparatus with means for viewing the images (Figure 14A, Element 218).

**Claim 13/12:** Carroll '165 doesn't specifically teach an optical arrangement for focusing each of the detectors on a same region in the interior of

the breast. However, Siczek'447 teaches moving the beams to obtain two views of the breast to obtain the spatial coordinated or in other words the same region (Col. 9, Line 15-19). It would have been obvious to combine the teachings of Carroll'165 and Siczek'447 in order to locate the lesion for diagnosis (Col. 9, Line 19-22).

**Claim 14/12:** Carroll'165 teaches an apparatus wherein the matching interface comprises a surface of a transparent non-porous material and the breast (Col. 14, Line 60 – Col. 15, Line 4).

**Claim 15/12:** Carroll'165 teaches an apparatus wherein the imaging detectors are matrix detectors (Col. 12, Line 24-50 & Figure 8A).

**Claim 16/12:** Carroll '165 teaches an apparatus wherein the imaging detectors comprise video cameras (Figure 14A, Element 186).

**Claim 18/12:** Carroll'165 teaches an apparatus wherein the imaging detectors comprise photographic film (Col. 15, Line 19-21).

**Claim 19/1:** Carroll '165 teaches an apparatus a breast cage for supporting the breast during imaging (Figure 12, Element 152).

18. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll'165 (US Patent No. 4,515,165), in view of Siczek'447 (US Patent No. 5,386,447) and in further view of Nelson'974 (US Patent No. 4,948,974).

**Claim 17/12:** Carroll'165 fails to teach CCD arrays. Nelson'974 teaches an apparatus wherein the imaging detectors comprise CCD arrays (Col. 7, Line 27-32). It would have been obvious to combine the teachings of Carroll'165 and

Nelson'974 in order to record the intensities of the spatially separated components (Col. 7, Line 31-32).

***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Godik; Eduard E. Optical Functional Mamoscope. US 5730133 A.

b. Godik; Eduard E. Method for Investigation of Distribution of Physiological Components in Human Body Tissues and Apparatus for its Realization. US 5747789 A.

c. Abdel-Mottaleb; Mohamed. Mass Detection in Digital X-ray Images Using Multiple Threshold Levels to Discriminate Spots. US 5768406 A.

d. Benaron; David A. et al. Tissue Interrogating Device and Methods. US 5769791 A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

ELENI MANTIS MERCADER
SPE ART UNIT 3768